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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,416	03/29/2001	David Bar-Or	4172-15-1	5597

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SHERIDAN ROSS PC
1560 BROADWAY
SUITE 1200
DENVER, CO 80202

EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/02/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/820,416

Applicant(s)

BAR-OR ET AL.

Examiner

Khatol S Shannan-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-101 is/are pending in the application.
- 4a) Of the above claim(s) 54,55,59,62,65 and 69-101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-53,56-58,60,61,63,64 and 66-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 48-101 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,8,10,12</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants preliminary amendment A, received July 27, 2001, paper # 7 is acknowledged.

Claims 1-47 were canceled. New claims 48-101 were added.

Information Disclosure Statement

2. Information disclosure statements, received July 27, 2001 and November 14, 2001, papers # 5 and # 8 are acknowledged. No copies of the references were submitted. Applicants referred to the priority application Serial No. 09/165,961 for those documents. The examiner has tried to locate the references and for the time being does not have access to the parent file, therefore the references have not been considered by the examiner (see attached 1449 forms)

However, supplemental information disclosure statements, received March 25, 2002 and May 6, 2002, papers # 10 and # 12 are acknowledged and considered by the examiner (see attached 1449 forms).

Election/Restrictions

3. Applicants' election with out traverse of April 04, 2002 in Paper No. 11 is acknowledged. Applicants elected Group I (claims 48-68), directed to a method of monitoring treatment of disease with a compound that produces or reduces free radical damage, by quantifying the presence of the marker albumin. For the election of the species applicant elected "produce" from claim 48, superoxide dismutase from claim 50, serum from claim 53 cobalt from claims 57 and 68 and atomic absorption from claim 58.
4. Claims 54-55, 59, 62, 65 and 69-101, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non elected inventions.
5. Currently claims 48-101 are pending.

6. Claims 48, 49, 50-53, 56-58, 60-61, 63-64 and 66- 68 are under consideration.

Priority

7. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a continuation of Application No. PCT/US99/22746, filed 10/11/1999 which is a CIP of Application No. 09/165,961, filed 10/02/1998." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 48, 49, 50-53, 56-58, 60-61, 63-64 and 66- 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 48 recites the limitation "modified albumin" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for reciting improper Markush group. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being “



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selected from the group comprising of A, B, and/or C.” See *ex parte Markush*, 1925 C.d. 126 (Comm’r Pat. 1925).

Claims 49, 50-53, 56-58, 60-61, 63-64 and 66- 68 are rejected as being dependent from indefinite claim 48.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 48, 49, 50-53, 56-58, 60-61, 63-64 and 66- 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-Or et al. (US Patent No: 5,227,307) in view of Crapo et al. (US Patent No. 5,994,339) and further in view of Young et al. (6,375,930).

Claims are drawn to a method of monitoring or assessing treatment of a disease or condition with a compound that produces free radicals comprising:

- a) obtaining a biological sample;
- b) treating the patient with a compound;
- c) obtaining additional biological samples after treatment; and determining the change of albumin in the sample by:
- d) contacting each of the biological sample with excess quantity of a metal ion salt;
- e) determining the amount of bound metal ion to the albumin;
- f) determining if there is a change in the amount of bound metal ion.

Bar-Or et al. (US Patent No: 5,227,307) teach a method of monitoring disease or condition in a patient that produces free radicals comprising:

- a) obtaining a biological sample and determining the change of albumin in the sample by:
- b) contacting each of the biological sample with excess quantity of a metal ion salt;
- c) determining the amount of bound metal ion to the albumin;
- d) determining if there is a change in the amount of bound metal ion.

(see abstract and claims).

Bar-Or et al. teach a method for detecting ischemic states (lack of oxygen) in a patient by contacting a sample of serum with a metal ion capable of binding to metal binding sites in the sample to form a mixture and then detecting the presence of unbound metal ion to determine the ischemic event (see example 1 and claims). Furthermore, the prior art teaches that several methods could be used to measure the metal ion binding to the albumin such as atomic absorption, atomic emission spectroscopy and determining the color intensity by spectrophotometer (see column 3, lines 44-54). Bar-Or et al. teach a variety of metal ion salts including cobalt (see column 5, lines 23-40). Bar-Or et al. teach that the quantity of free metal ions in the sample may also be detected by colorimetric means and teach a variety of color forming compounds (see column 6, lines 20-65). Bar-Or et al. (US Patent No: 5,290,519) teach a method of quantifying modified albumin, column 3, lines 14-22 recite that “ In the present method, a sample of serum, plasma, fluid or tissue from a patient is reached with metal ions, generally in the form of an aqueous salt solution, so that the metal ion become bound to the metal binding sites on the protein in the sample. Metal ions bind to the proteins containing metal ion- binding sites such as thiol, hydroxy, carboxy, amino groups present on the amino acids which constitute the protein.” Therefore, Bar-Or et al. teach modified protein (i.e. modified albumin) since metal binding capacity is reduced or inhibited in the

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albumin. Bar-Or et al. do not teach treating patient with a compound or superoxide dismutase as a free radical scavenger. However, Crapo et al. teach treating patient with an effective amount of a mimetic of superoxide dismutase as a free radical scavenger (see column 1, background, column 2, summary of invention and claims specially claim 1). Crapo et al. do not teach photosensitizing agents and porfimer sodium. However, Young et al. teach photodynamic therapy and porfimer sodium (see column 3, lines 10-20 and column 4, lines 50-56). It would have *prima facie* obvious to a person of ordinary skill in art at the time the invention was made to use and combine the methods set forth in Bar-Or et al., Crapo et al. and Young et al. to obtain the claimed invention. One of ordinary skill in art would have been motivated with the reasonable expectation of success to develop a method of monitoring or assessing treatment of a disease by detecting or quantifying free radical damage as taught by Bar-Or et al. absent any convincing evidence to the contrary.

Conclusion

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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June 25, 2002


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER